THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION	Master Docket No. 19-2875 (RBK/JS)
SARAH ZEHR, on behalf of herself and all others similarly situated, Plaintiff, v. ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., PRINSTON PHARMACEUTICAL, INC., dba SOLCO HEALTHCARE U.S., LLC, SOLCO HEALTHCARE US, LLC, and HUAHAI U.S., INC., Defendants.	**COMPLAINT AND JURY DEMAND** CLASS ACTION Civil Action No._____

CLASS ACTION COMPLAINT FOR MEDICAL MONITORING
CLASS OF RESIDENTS & CITIZENS OF THE STATE OF FLORIDA

1. Plaintiff Sarah Zehr, individually and on behalf of all others similarly situated who are residents or citizens of the State of Florida, brings this Complaint for medical monitoring against the Defendants identified below on the grounds set forth below and pursuant to the statutory, regulatory and decisional law of the State of Florida.

2. Plaintiff files this Complaint in accordance with Case Management Order No. 3 of this Court.

PARTIES

Plaintiff

3. Plaintiff Sarah Zehr is a resident and citizen of the State of Florida and was so at all times relevant to this Complaint.

Defendants: Active Pharmaceutical Manufacturers

4. Defendant **Zhejiang Huahai Pharmaceutical Co., Ltd.** ("Zhejiang") is a Chinese corporation with its principal place of business at Xunqiao, Linhai, Zhejiang 317024, China. The company also has a United States headquarters located at 2009 Eastpark Blvd., Cranbury, NJ 08512.

5. Zhejiang is the parent company of subsidiaries Prinston Pharmaceutical Inc., Solco Healthcare, LLC, and Huahai U.S., Inc.

6. The drugs that are the subject of this action are made by Zhejiang and are distributed in the United States by three companies: Major Pharmaceuticals; Teva Pharmaceutical Industries, Ltd.; and Solco Healthcare.

Defendants: Drug Manufacturers

7. Defendant **Prinston Pharmaceutical, Inc., dba Solco Healthcare US, LLC** ("Prinston") is a Delaware corporation with its principal place of business at 2002 Eastpark Blvd., Cranbury, New Jersey 08512.

8. Defendant **Solco Healthcare U.S., LLC** ("Solco") is a fully-owned subsidiary of Prinston Pharmaceutical, Inc. and Zhejiang Huahai Pharmaceutical Co, Ltd.

9. Solco is a Delware corporation with its principal place of business located at 2002 Eastpark Boulevard, Suite A, Cranbury, New Jersey 08512.

Defendants: Other Entities

10. Defendant Huahai U.S., Inc. ("Huahai") is a New Jersey corporation with its principal place of business at 2001 (and 2002) Eastpark Boulevard, Cranbury, NJ 08512.

11. Huahai is a subsidiary of Zhejiang Huahai Pharmaceutical Ltd., Co.

JURISDICTION AND VENUE

12. This Court has **subject matter jurisdiction** over this action pursuant to 28 U.S.C. § 1332, because there is complete diversity of citizenship between Plaintiff and the Defendants, and because Plaintiff alleges an amount in controversy in excess of $75,000, exclusive of interest and costs.

13. Further, this Court has **subject matter jurisdiction** over this action pursuant to CAFA, Pub. L. 109-2, 119 Stat. 4 (codified in scattered sections of Title 28 of the United States Code), under 28 U.S.C. § 1332(d), which provides for the original jurisdiction of the federal district courts over "any civil action in which the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs, and [that] is a class action in which . . . any member of a class of plaintiffs is a citizen of a State different from any defendant." 28 U.S.C. § 1332(d)(2)(A). Plaintiff is diverse from all Defendants and Plaintiff seeks to represent other Class members who are diverse from all Defendants. Plaintiff alleges the matter in controversy exceeds $5,000,000.00 in the aggregate, exclusive of interest and costs. Finally, "the number of members of all proposed plaintiff classes in the aggregate" is greater than 100. See 28 U.S.C. § 1332(d)(5)(B).

14. This Court has **personal jurisdiction** over Defendants Zhejiang, Prinston, Solco, and Huahai because these Defendants reside in this district, have headquarters and/or their principal places of business within the State of New Jersey, and otherwise are "at home" in the State of New Jersey.

15. This Court has **personal jurisdiction** over all Defendants because all have purposefully availed themselves of the privilege of doing business within the state; have had continuous and systematic general business contacts within the state; and Defendants can be said to have reasonably anticipated being haled into court in this forum.

16. **Venue** is proper in this district pursuant to 28 U.S.C. § 1391(a) because a substantial portion of the wrongful acts upon which this lawsuit is based occurred in this District insofar as they emanated from the headquarters of Defendants at home in this state.

17. **Venue** is proper pursuant to 28 U.S.C. § 1391(c), because the Court has personal jurisdiction over Defendants, deeming them residents of this District, and because the Defendants not resident in the United States may be sued in any judicial district.

18. **Venue** is proper in this district because the Judicial Panel on Multidistrict Litigation has transferred all such actions to this district pursuant to 28 U.S.C. § 1407.

19. The District Court in which remand trial is proper and where Plaintiff might have other filed this Complaint absent the CMO 3 direct filing order by This Court is the Northern District of Florida.

FACTUAL ALLEGATIONS

Plaintiff's Medication

20. The medication in question in this case is a drug that Defendants marketed and sold under the name "valsartan."

21. Valsartan is a generic version of the brand-name medication, Diovan.

22. Valsartan is used to treat high blood pressure and heart failure and to improve a patient's chances of living longer after a heart attack.

23. Valsartan is classified as an angiotensin receptor blocker (ARB) that is selective for the type II angiotensin receptor. It is intended to work by relaxing blood vessels so that blood can flow more easily, thereby lowering blood pressure.

24. Valsartan can be sold by itself or as a single pill which combines valsartan with amlodipine or HCTZ, or both.

25. The drug binds to angiotensin type II receptors (AT1) and works as an antagonist.

26. The patents for Diovan and Diovan/hydrochlorothiazide expired in September 2012.

27. Shortly after the patent for Diovan expired, the FDA began to approve generic versions of the drug, such as Valsartan.

N-Nitrosodimethylamine (NDMA)

28. N-nitrosodimethlyamine, commonly known as NDMA, is an odorless, yellow liquid.

29. NDMA is a semivolatile chemical that forms in both industrial and natural processes.

30. NDMA can be unintentionally produced in and released from industrial sources through chemical reactions involving other chemicals called alkylamines.

31. NDMA is a form of nitrosamine and is structurally related to the tobacco-specific nitrosamine 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), which is one of the most potent carcinogens among the many carcinogens found in cigarette smoke.

32. NDMA has been shown to be carcinogenic (capable of causing cancer), mutagenic (capable of causing gene mutation), tumorigenic (capable of causing tumors), and teratogenic (capable of causing birth defects).

33. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.

34. The US Department of Health and Human Services (DHHS) classifies NDMA as reasonably anticipated to be a human carcinogen. This classification is based upon DHHS's findings that NDMA caused tumors in numerous species of experimental animals, at several different tissue sites, and by several routes of exposure, with tumors occurring primarily in the liver, respiratory tract, kidney, and blood vessels.

35. Exposure to NDMA can occur through ingestion of food, water, or medication containing nitrosamines.

36. Exposure to NDMA has proven tumorigenic in rats, particularly in rat livers.

37. Exposure to high levels of NDMA has been linked to liver damage in humans.

38. According to the Agency for Toxic Substances and Disease Registry, "NDMA is very harmful to the liver of humans and animals. People who were intentionally poisoned on one or several occasions with unknown levels of NDMA in beverage or food died of severe liver damage accompanied by internal bleeding."

39. Other studies showed an increase in other types of cancers, including cancers of the stomach, colorectal tract, intestinal tract, and other digestive tracts.

40. On July 27, 2018, the FDA issued a press release explaining its concern over the presence of NDMA found in valsartan-containing drugs:

> NDMA has been found to increase the occurrence of cancer in animal studies…Consuming up to 96 nanograms NDMA/day is considered reasonably safe for human ingestion.… The amounts of NDMA found in the recalled batches of valsartan exceeded these acceptable levels.

41. The Environmental Protection Agency classified NDMA as a probable human carcinogen "based on the induction of tumors at multiple sites in different mammal species exposed to NDMA by various routes."

N-Nitrosodiethylamine (NDEA)

42. N-Nitrosodiethylamine, often referred to as NDEA, is a yellow, oily liquid that is highly soluble in water.

43. Like NDMA, NDEA is also classified as a probable human carcinogen and a known animal carcinogen.

44. NDEA is an even more potent carcinogen than NDMA.

45. According to the U.S. Environmental Protection Agency, even short-term exposure to NDEA can damage the liver in humans. Animal studies also demonstrate that chronic ingestion of NDEA can cause liver tumors and other types of tumors as well, including in the kidneys.

46. Hematological effects were also reported in animal studies.

47. Tests conducted on rats, mice, and hamsters demonstrate that NDEA has high to extreme toxicity from oral exposure.

48. The New Jersey Department of Health notes that NDEA "should be handled as a CARCINOGEN and MUTAGEN – WITH EXTREME CAUTION."

49. The New Jersey Department of Health also states that "[t]here may be no safe level of exposure to a carcinogen, so all contact should be reduced to the lowest possible level."

50. The New Jersey Department of Health notes that NDEA is classified as a probable human carcinogen, as it has been shown to cause liver and gastrointestinal tract cancer, among others.

Formation of Nitrosamines in the Drug

51. NDMA and NDEA both are considered genotoxic compounds, as both contain nitroso groups, which are gene-mutating groups.

52. Upon information and belief, the reason Defendants' manufacturing process produced these compounds is linked to the tetrazole group that most ARB drugs have. Solvents used to produce the tetrazole ring, such as N-Dimethylformamide (DMF), can result in the formation of drug impurities or new active ingredients, such as NDMA and NDEA, as a byproduct of the chemical reactions.

53. The pharmaceutical industry has been aware of the potential for the formation of nitrosamines in pharmaceutical drugs since at least 2005.

Recalls

54. Upon information and belief, the presence of NDMA and NDEA in the subject drugs is due to a manufacturing change that took place on or around 2012.

55. On July 13, 2018, the FDA announced a recall of certain batches of valsartan-containing drugs after finding NDMA in the recalled product. The products subject to this recall were some of those which contained the active pharmaceutical ingredient (API) supplied by Defendant Zhejiang.

56. FDA noted that the valsartan-containing drug being recalled "does not meet our safety standards."

57. The recall notice further stated, "Zhejiang Huahai Pharmaceuticals has stopped distributing its valsartan API and the FDA is working with the affected companies to reduce or eliminate the valsartan API impurity from future products."

58. FDA placed Zhejiang on import alerts, which halted all API made by the company from entering the United States. This was the result of an inspection of Zhejiang Huahai's facility.

59. FDA's recall notice also stated that the presence of NDMA in the valsartan-containing drugs was "thought to be related to changes in the way the active substance was manufactured."

60. The recall was limited to "all lots of non-expired products that contain the ingredient valsartan supplied to them by [the Active Pharmaceutical Manufacturer (API)] supplied by this specific company."

61. On July 18, 2018, FDA put out another press release about the recall, noting its determination that "the recalled valsartan products pose an unnecessary risk to patients."

62. After the initial recall in July, 2018, the list of valsartan-containing medications discovered to contain NDMA continued to grow.

63. On August 9, 2018, FDA announced that it was expanding the recall to include valsartan-containing products manufactured by another API manufacturer, Hetero Labs Limited, labeled as Camber Pharmaceuticals, Inc., as these recalled pills also contained unacceptable levels of NDMA. FDA noted, "Hetero Labs manufactures the API for the Camber products using a process similar to Zhejiang Huahai Pharmaceuticals."

64. On October 5, 2018, FDA posted the results of some testing conducted on samples of recalled valsartan tablets. Noting that "consuming up to 0.096 micrograms of NDMA per day is considered reasonably safe for human ingestion based on lifetime exposure," the results of the testing showed levels ranging from 0.3 micrograms up to 17 micrograms.

65. Thus, the pills contained somewhere between 3.1 and 177 times the level of NDMA deemed safe for human consumption. Subsequent testing revealed levels as high as 20 micrograms, which is 208.3 times the safe level.

66. By way of comparison, NDMA is sometimes also found in water and foods, including meats, dairy products, and vegetables. The U.S. Health Department set strict limits on the amount of NDMA that is permitted in each category of food, but these limits are dwarfed by the amount of NDMA present in the samples of the valsartan-containing medications referenced above.

67. On November 21, 2018, FDA announced a new recall, this time because NDEA was detected in the tablets. Additional recalls of valsartan-containing tablets which were found to contain NDEA followed. These recall notices also stated that the recalls related to unexpired valsartan-containing products.

68. Over the course of the fall and winter of 2018, NDMA and NDEA continued to be detected across so many brands of valsartan and other ARB drugs that the FDA imposed interim limits for NDMA and NDEA in ARBs to prevent drug shortages. In doing so, FDA reminded "manufacturers that they are responsible for developing and using suitable methods to detect impurities, including when they make changes to their manufacturing processes. If a manufacturer detects a new impurity or high level of impurities, they should fully evaluate the impurities and take action to ensure the product is safe for patients."

Recalls in Other Countries

69. The European Medicines Agency (EMA) also recalled many batches of valsartan-containing drugs. According to the agency, "[t]he review of valsartan medicines was triggered

by the European Commission on 5 July 2018…. On 20 September 2018, the review was extended to include medicines containing cadesartan, Irbesartan, losartan and Olmesartan."

70. In light of the EMA's findings, Defendant Zhejiang, along with another API manufacturer, Zhejiang Tianyu, are not authorized to produce valsartan for medications distributed in the European Union.

71. Health Canada also issued a recall of valsartan-containing medications on July 9, 2018, noting the presence of NDMA as the reason. Health Canada similarly stated that NDMA is a potential human carcinogen.

The Federal Regulatory Regime: Generic Drugs

72. According to FDA, "[a] generic drug is a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. These similarities help to demonstrate bioequivalence, which means that a generic medicine must work in the same way and provides the same clinical benefit as its brand-name version. In other words, you can take a generic medicine as an equal substitute for its brand-name counterpart."

73. While brand-name medications undergo a more rigorous review before being approved, generic manufacturers are permitted to submit an abbreviated new drug application (ANDA), which only requires a generic manufacturer to demonstrate that the generic medicine is the same as the brand name version in the following ways:

a. The active ingredient in the generic medicine is the same as in the brand-name drug/innovator drug.

b. The generic medicine has the same strength, use indications, form (such as a tablet or an injectable), and route of administration (such as oral or topical).

c. The inactive ingredients of the generic medicine are acceptable.

d. The generic medicine is manufactured under the same strict standards as the brand-name medicine.

e. The container in which the medicine will be shipped and sold is appropriate, and the label is the same as the brand-name medicine's label.

74. The subject drugs ingested by Plaintiff were approved by the FDA, which assumed based upon Defendants' representations that these drugs met the above criteria.

75. ANDA applications do not require drug manufacturers to repeat animal studies or clinical research on ingredients or dosage forms already approved for safety and effectiveness.

76. Further, because generic drugs are supposed to be nearly identical to their brand-name counterparts, they also are supposed to have the same risks and benefits.

The Federal Regulatory Regime: Misbranded & Adulterated Drugs

77. The manufacture of any misbranded or adulterated drug is prohibited by federal law.

78. The introduction into commerce of any misbranded or adulterated drug is prohibited.

79. The receipt in interstate commerce of any adulterated or misbranded drug also is unlawful.

80. A drug is adulterated:

a. if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;

b. if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice…as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess;

c. If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and … its quality or purity falls below, the standard set forth

in such compendium. … No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label; and./or

d. If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

81. A drug is misbranded:

a. If its labeling is false or misleading in any particular;

b. If any word, statement, or other information required…to appear on the label or labeling is not prominently placed thereon…in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

c. If the labeling does not contain, among other things, "the proportion of each active ingredient.

d. Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings … against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users;

e. If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein;

f. if it is an imitation of another drug;

g. if it is offered for sale under the name of another drug;

h. If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof;

i. If the drug is advertised incorrectly in any manner; and/or

j. If the drug's "packaging or labeling is in violation of an applicable regulation.

82. As articulated in this Complaint, Defendants' unapproved drug was misbranded and adulterated in violation of all of the above-cited reasons.

83. Adulteration and misbranding constitute evidence of negligence under Florida law.

Plaintiff Ingested Not Valsartan, But a New, Unapproved Valsartan-Containing Drug

84. The FDA's website provides the definition for a drug:

> The Federal Food Drug and Cosmetic Act (FD&C Act) and FDA regulations define the term drug, in part, by reference to its intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." Therefore, almost any ingested or topical or injectable product that, through its label or labeling (including internet websites, promotional pamphlets, and other marketing material), is claimed to be beneficial for such uses will be regulated by FDA as a drug." The definition also includes components of drugs, such as active pharmaceutical ingredients.

85. The FDA's website provides the definition for an active ingredient:

> 21 C.F.R. § 210.3(b)(7) defines an "active ingredient" in a drug as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect."

86. NDMA and NDEA both have the ability to cause cancer by triggering genetic mutations in humans. This mutation affects the structure of the human body, and thus, NDMA and NDEA are, by definition, active ingredients in a drug.

87. FDA further requires that whenever a new, active ingredient is added to a drug, then the drug becomes an entirely new drug, necessitating a submission of a New Drug Application by the manufacturer. Absent such an application, followed by a review and approval by the FDA, this new drug remains a distinct, unapproved product.

Defendants Have No Federal Preemption Defense Because They Did Not Adhere to the Terms of ANDA Approval or Obtain FDA Approval for Their New Drugs.

88. Generic labels are required to be the same as the corresponding brand-name labels.

89. When a generic manufacturer stops manufacturing a drug that meets all terms of its approval, or in other words, when the drug is not the same as its corresponding brand-name drug, then the manufacturer has created an entirely new (and unapproved) drug.

90. This new and unapproved drug cannot be required to have the same label as the brand-name drug, as the two products are no longer the same. Thus, the manufacturer forfeits the shield of federal preemption.

91. Therefore, Plaintiff's state-law claims asserted herein do not conflict with the federal regulatory scheme.

92. At the very least, and alternatively, drugs with different and dangerous ingredients than their brand-name counterparts are adulterated under federal law, and the sale or introduction into commerce of adulterated drugs is illegal. Thus, a plaintiff bringing a state-law tort claim premised upon this violation is not asking the manufacturer to do anything different than what federal law already requires.

93. Plaintiff references federal law herein not in any attempt to enforce it, but only to demonstrate that Plaintiff's state-law tort claims do not impose any additional obligations on Defendants beyond what is already required of them under federal law.

94. Because the valsartan-containing drugs ingested by Plaintiff were never approved or even reviewed by the FDA, the FDA never conducted an assessment of safety or effectiveness for these drugs.

Defendants' False Statements in the Labeling of Valsartan-Containing Drugs

95. A manufacturer is required to give adequate directions for the use of a pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended," and conform to requirements governing the appearance of the label.

96. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device, and therefore broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising.

97. Most, if not all, labeling is advertising. The term "labeling" is defined in the FDCA as including all printed matter accompanying any article. Congress did not exclude from the definition printed matter which constitutes advertising.

98. If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded.

99. Because NDMA and/or NDEA were not disclosed by Defendants as ingredients in the valsartan-containing drugs ingested by Plaintiff, the subject drugs were misbranded.

100. It is unlawful to introduce a misbranded drug into interstate commerce.

101. Accordingly, the valsartan-containing drugs ingested by Plaintiff were unlawfully distributed and sold.

102. Misbranding and mislabeling constitute evidence of negligence under Florida law.

Adherence to Good Manufacturing Practices

103. In manufacturing, distributing, and selling the contaminated valsartan-containing drugs ingested by Plaintiff, Defendants violated Current Good Manufacturing Practices (cGMP).

104. Under 21 C.F.R. § 200 *et seq.*, cGMP requirements are set forth. The requirements in this part are intended to ensure that drugs will be safe and effective and otherwise in compliance with the FDCA and the part establishes basic requirements applicable to manufacturers of pharmaceutical drugs.

105. Specifically, 21 C.F.R. § 201.6 states that "[t]he labeling of a drug which contains two or more ingredients may be misleading by reason, among other reasons, of the designation

of such drug in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling."

106. Section 201.10 requires that all ingredients (meaning "any substance in the drug, whether added to the formulation as a single substance or in admixture *[sic]* with other substances) be listed. Failure to reveal the presence of an ingredient when the ingredient is material to the drug renders the drug misbranded.

107. Section 201.56 provides requirements for drug labeling including (1) that the labeling must contain a summary of the essential scientific information needed for the safe and effective use of the drug; (2) that the labeling must be accurate and must not be misleading; and (3) that labeling must be based upon human data, and no claims can be made if there is insufficient evidence of effectiveness.

108. Further, any new labels submitted to the FDA must contain all information outlined in the regulation. This includes providing adequate warnings about serious and frequently occurring adverse reactions. This also may include providing boxed warnings for adverse reactions that may lead to death or serious injury.

109. Clinically significant adverse reactions also should be listed in the Warnings and Precautions section of the label. The label also must provide information about whether long term studies in animals have been performed to evaluate carcinogenic potential.

110. Section 202.1 covers prescription-drug advertisements and requires that the ingredients of the drug appear in ads. Ads must also contain true statements of information relating to side effects.

111. Parts 211, 225, and 266 "contain the minimum current good manufacturing practices for the methods used in, and the facilities or controls to be used for, the manufacture, processing, packaging, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess." 21 C.F.R. 210.1(a). Failure to comply with any of these regulations renders a drug adulterated. 21 C.F.R. 210.1(b).

112. Section 210.3(7) defines an "active ingredient" in a drug to mean "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect."

113. Section 211.22 requires that a quality control unit be charged with ensuring quality requirements are met and the personnel are adequately trained.

114. Sections 211.42-58 require that facilities be kept in good repair, that adequate lighting, ventilation, and temperature conditions be maintained.

115. Sections 211.100-211.115 require manufacturers to have written procedures for production and process control to ensure consistency and quality. These procedures should also require thorough documentation of any deviations from these procedures.

116. Section 211.160 require that manufacturers maintain written standards, sampling plans, test procedures, or other laboratory control mechanisms, including sampling procedures and plans, and that those standards be reviewed by a quality control unit. All deviations from these procedures should be documented.

117. Sections 211.165, 211.166, and 211.170 require that appropriate sampling and stability testing be done, and that samples be retained for testing.

118. Sections 211.180-211.198 require written records of maintenance, laboratory records, distribution records, and complaint files, among other things.

119. Failure to adhere to cGMPs constitutes evidence of negligence under Florida law.

Defendants' Knowledge

120. At all relevant times, the valsartan-containing drugs ingested by Plaintiff were researched, developed, manufactured, marketed, promoted, advertised, sold, designed and/or distributed by Defendants.

121. Defendants knew—or in the exercise of reasonable care, should have known—that that the valsartan-containing drugs ingested by Plaintiff were defective, unreasonably dangerous, and not safe for the purposes and uses that these Defendants intended.

122. Defendants knew—or in the exercise of reasonable care, should have known—that the valsartan-containing drugs ingested by Plaintiff were defective, unreasonably dangerous and not safe for human consumption, as they contained dangerously high levels of the carcinogenic compounds NDMA and NDEA.

123. Defendants misrepresented, downplayed, and/or omitted the safety risks of the valsartan-containing drugs Plaintiff ingested by failing to disclose the presence of NDMA and/or NDEA in their products and by failing to disclose the side effects associated with ingesting these compounds at dangerously high levels.

124. Defendants willfully and/or intentionally failed to warn and/or alert physicians and patients, including Plaintiff, Plaintiff's physicians, and all members of the proposed Class, of the

increased risks and significant dangers resulting from the FDA-unapproved use of the valsartan-containing drugs ingested by Plaintiff, which contained carcinogenic compounds.

125. Defendants failed to conduct proper testing relating to the unapproved drugs they manufactured, distributed, marketed, and sold to Plaintiff and Plaintiff's physicians.

126. Defendants failed to seek FDA approval for the unapproved drugs they manufactured, distributed, marketed, and sold to Plaintiff and Plaintiff's physicians.

127. Defendants failed to sufficiently conduct post-market surveillance for the unapproved drugs they manufactured, distributed, marketed, and sold to Plaintiff and Plaintiff's physicians.

128. The ongoing scheme described herein could not have been perpetrated over a substantial period of time, as has occurred here, without knowledge and complicity of personnel at the highest level of Defendants, including the corporate officers.

129. Defendants knew—or in the exercise of reasonable care, should have known—of the likelihood of exposure to serious latent disease caused by the use of the valsartan-containing drugs ingested by Plaintiff; but they concealed this information and did not warn Plaintiff, Plaintiff's physicians, or any member of the Class of such dangers.

130. Defendants knew—or in the exercise of reasonable care, should have known—that the manufacturing processes employed to make the valsartan-containing drugs Plaintiff and Class members ingested were unreasonably dangerous, unsafe, unvalidated, and not properly studied or tested.

131. Defendants knew—or in the exercise of reasonable care, should have known—that it is the manufacturer's duty to test its products to ensure they meet quality and safety standards. Yet, Defendants failed to do so.

132. Had Defendants performed adequate tests on the valsartan-containing drugs, they would have discovered that these drugs were not safe for human consumption.

133. Had Defendants performed adequate tests on the valsartan-containing drugs, neither Plaintiff nor any member of the proposed class would require

PLAINTIFF-SPECIFIC ALLEGATIONS

134. Between approximately May of 2016 and November of 2018, Plaintiff Sarah Zehr was prescribed and ingested generic valsartan to treat high blood pressure.

135. The valsartan ingested by Plaintiff was manufactured by the above-captioned defendants and was at least in part subject to the recent recall of valsartan issued by the United States Food and Drug Administration.

136. As a direct and proximate result of ingesting the valsartan, Plaintiff was exposed to levels of NDMA and NDEA that exceed background levels of those compounds.

137. NDMA and NDEA have been proven to be hazardous substances.

138. Plaintiff's exposure to NDMA and NDEA was a direct and proximate result of Defendants' negligence.

139. As a direct and proximate result Plaintiff's exposure to NDMA and NDEA through ingestion of valsartan, Plaintiff has a significantly increased risk of contracting a latent disease or diseases including (a) liver cancer; (b) intestinal cancers (including colorectal cancer); (c) stomach cancer; (d) kidney cancer; (e) pancreatic cancer; and (f) esophageal cancer.

140. Monitoring procedures exist that make the early detection of these diseases possible.

141. Such monitoring procedures are different from those normally recommended in the absence of exposure to NDMA and NDEA.

142. Such monitoring procedures are reasonably necessary for Plaintiff and members of the proposed Class based on contemporary scientific principles.

143. As a direct and proximate result of these Defendants' wrongful conduct and the use of Defendants' defective medications, Plaintiff and members of the proposed Class suffer and will continue to suffer the costs of periodic medical examinations necessary to detect the onset of physical harm caused by NDMA and/or NDEA.

CLASS ALLEGATIONS

Class Definition

144. The class is defined as: *All residents and citizens of Florida who have ingested valsartan-containing drugs and who are asymptomatic for cancer*.

145. Excluded from the Class are: (a) Defendants, Defendants' board members, executive-level officers, and attorneys, and immediately family members of any of the foregoing persons; (b) governmental entities; (c) the Court, the Court's immediate family, and the Court staff; and (d) any person that timely and properly excludes himself or herself from the Class in accordance with Court-approved procedures.

146. Plaintiff reserves the right to alter the Class definitions as deemed necessary at any time to the full extent that the Federal Rules of Civil Procedure, the Local Rules of the United States District Court of New Jersey, and applicable precedent allow.

Specific Class Allegations

147. Certification of Plaintiff's claims for class-wide treatment is appropriate because Plaintiff can prove the elements of the claims on a class-wide basis using the same evidence as individual Class members would use to prove those elements in individual actions alleging the same claims.

148. Numerosity; Rule 23(a)(1): The size of the Class is so large that joinder of all Class members is impracticable. Due to the nature of Defendants' business and the size of the recent recall, Plaintiff believes there are thousands of Class members geographically dispersed throughout the State of Florida.

149. Existence and Predominance of Common Questions of Law and Fact; Rule 23(a)(2), (b)(3): There are questions of law and fact common to the Class. These questions predominate over any questions affect only individual Class members. Common legal and factual questions include but are not limited to:

a. whether Defendants sold valsartan-containing drugs that were recalled or subject to a recall;

b. the nature and extent of Defendants' representations and omissions concerning the subject drugs;

c. whether Defendants were negligent in the manufacturing of the subject drugs;

d. whether Defendants were negligent in the design of the subject drugs;

e. whether Defendants were negligent in the advertising, marketing, testing, quality control, and post-market surveillance of the drugs and whether Defendants otherwise were negligent;

f. whether the subject drugs were defectively designed and/or defectively manufactured;

g. whether Defendants' negligence and/or the defective nature of the subject drugs caused Plaintiff and the class to be exposed to levels of NDMA or NDEA that are significantly higher than background levels;

h. the increased risk of disease for Plaintiff and the Class based upon their exposure to NDMA or NDEA;

i. the existence and nature of procedures for monitoring Plaintiff and the Class for the various diseases for which they now are at increased risk;

j. whether a monitoring regime is reasonably necessary based upon contemporary scientific standards; and

k. the cost of implementing a proper monitoring regime to address Plaintiff's claims and those of the Class.

150. Defendants engaged in a common course of conduct in contravention of the laws Plaintiff seeks to enforce individually and on behalf of the Class members. Similar or identical violations of law, business practices, and injuries are involved. Individual questions, if any, pale by comparison, in both quality and quantity, to the numerous common questions that dominate this action. Moreover, the common questions will yield common answers that will substantially advance the resolution of the case.

151. Typicality; Rule 23(a)(3): Plaintiff's claims are typical of the claims of the Class members because Defendants injured all Class members through the uniform misconduct described herein; all Class members suffered legal injury due to Defendants' negligence and defective products (i.e., increased exposure to carcinogens giving rise to a medical need for future monitoring); and Plaintiff seeks the same relief as the Class members.

152. There are no defenses available to Defendants that are unique to Plaintiff.

153. Adequacy of Representation; Rule 23(a)(4): Plaintiff is a fair and adequate representative of the Class because Plaintiff's interests do not conflict with the Class members' interests. Plaintiff will prosecute this action vigorously and is highly motivated to seek redress against Defendants. Furthermore, Plaintiff has selected competent counsel who are experienced in class action and other complex litigation. Plaintiff and Plaintiff's counsel are committed to prosecuting this action vigorously on behalf of the Class and Plaintiff's counsel have the resources to do so.

154. Injunctive or Declaratory Relief; Rule 23(b)(2): The requirements for maintaining a class action pursuant to Rule 23(b)(2) are met, as Defendant has acted or refused to act on

grounds generally applicable to the Class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the Class as a whole.

155. If a Class is not certified, Plaintiff and the Class will have to seek and obtain payment for medical monitoring that will be paid for by Plaintiff and the Class members, by their insurance carriers, or by public assistance programs—any of which would relieve Defendants of the obligations they have imposed on Plaintiff and the Class to obtain such monitoring and thus relieving the wrongdoers of their moral and legal responsibilities.

156. Superiority; Rule 23(b)(3): The class action mechanism is superior to other available means for the fair and efficient adjudication of this controversy for reasons including but not limited to the following:

a. Although costs of monitoring Plaintiff and the Class are not insignificant, the cost for any individual is small compared to the burden and expense of individual prosecution of the complex and extensive litigation needed to address Defendants' conduct.

b. Further, it would be virtually impossible for the Class members individually to redress effectively the wrongs done to them. Even if Class members themselves could afford such individual litigation, the court system could not. Individualized litigation would unnecessarily increase the delay and expense to all parties and to the court system and presents a potential for inconsistent or contradictory rulings and judgments. By contrast, the class action device presents far fewer management difficulties, allows the hearing of claims which might otherwise go unaddressed because of the relative expense of bringing individual lawsuits, and provides the benefits of single adjudication, economies of scale, and comprehensive supervision by a single court.

c. The prosecution of separate actions by individual Class members would create a risk of inconsistent or varying adjudications, which would establish incompatible standards of conduct for Defendant.

d. The prosecution of separate actions by individual Class members would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other Class members not parties to the adjudications or that would substantively impair or impede their ability to protect their interests.

157. Notice: Plaintiff and Plaintiff's counsel anticipate that notice to the proposed Class will be effectuated through recognized, Court-approved notice dissemination methods, which may include United States mail, electronic mail, Internet postings, and/or published notice.

CLAIMS FOR RELIEF

COUNT I: NEGLIGENCE
On Behalf of Plaintiff and the Class

158. Plaintiff hereby incorporates by reference all previous allegations as if alleged herein.

159. Plaintiff brings this claim for negligence individually and on behalf of the Class against all Defendants.

160. Plaintiff and the Class were within the foreseeable zone of risk of legal injury (including ultimately the foreseeable need for medical monitoring) in the event Defendants' valsartan-containing drugs were defective or contaminated or otherwise negligently formulated, tested, manufactured, produced, marketed or sold; which risk Defendants knew or should have known and which risk Defendants foresaw or should have foreseen.

161. Defendants owed Plaintiff and the Class members a duty to offer only safe, non-contaminated products for ingestion.

162. Through their failure, jointly and severally, to exercise due care, Defendants breached this duty by producing, processing, manufacturing, and offering for sale the Products that were defective, contaminated, adulterated, misbranded, mislabeled, unsafe and unhealthy.

163. Defendants, jointly and severally, further breached the duty of care to Plaintiff and the Class by failing to use sufficient quality control and good manufacturing practices; by failing to perform adequate testing, proper manufacturing, production, or processing; and by failing to

take sufficient measures to prevent the subject drugs from being offered for sale, sold, or ingested by humans.

164. Defendants knew—or in the exercise of reasonable care, should have known—that the Products presented an unacceptable risk of harm to Plaintiff and the Class and would result in damage that was foreseeable and reasonably avoidable.

165. As a direct and proximate result of Defendants' negligence, Plaintiff and the Class members have suffered loss and damages.

166. Specifically, Defendants' joint and several negligence proximately caused Plaintiff and the Class members to experience significantly increased risk for suffering several types of cancer as alleged above, thus requiring future monitoring and the costs associated with such.

167. Wherefore, Plaintiff prays for relief as set forth below, individually and on behalf of the Class, against all Defendants.

COUNT II: STRICT PRODUCT LIABILITY (DESIGN DEFECT)
On Behalf of Plaintiff and the Class

168. Plaintiff hereby incorporates by reference all previous allegations as if alleged herein.

169. Plaintiff brings this claim individually and on behalf of the Class for strict product liability (design defect) against all Defendants.

170. Defendants are the producers, manufacturers, and/or distributors of the subject drugs.

171. The subject drugs Defendants' possession in an unreasonably dangerous condition.

172. The subject drugs reached Plaintiff and the Class members without substantial change in condition, as expected.

173. The subject drugs, which, among other potential defects, contained unsafe levels of NDMA and NDEA, were in an unreasonably dangerous condition because (a) they failed to perform as safely as an ordinary consumer would expect when used as intended or when used in a manner reasonably foreseeable to Defendants; and (b) because the foreseeable risks of using the subject drugs outweighed the benefits, if any, of their use.

174. Plaintiff and the Class members used the products as intended and in a manner reasonably foreseeable to Defendants.

175. As a direct and proximate result of the defective design of the subject drugs, Plaintiff and the Class members have suffered loss and damages.

176. Specifically, the defective nature of the subject drugs proximately caused Plaintiff and the Class members to experience significantly increased risk for suffering several types of cancer as alleged above, thus requiring future monitoring and the costs associated with such.

177. Wherefore, Plaintiff prays for relief as set forth below, individually and on behalf of the Class, against all Defendants.

COUNT III: STRICT PRODUCT LIABILITY (MANUFACTURING DEFECT)
On Behalf of Plaintiff and the Class

178. Plaintiff hereby incorporates by reference all previous allegations as if alleged herein.

179. Plaintiff brings this claim individually and on behalf of the Class for strict product liability (manufacturing defect) against all Defendants.

180. Defendants are the producers, manufacturers, and/or distributors of the subject drugs.

181. The subject drugs left Defendants' possession in an unreasonably dangerous condition.

182. The subject drugs reached Plaintiff and the Class members without substantial change in condition, as expected.

183. The subject drugs were unreasonably dangerous because they were different from their intended design and failed to perform as safely as the intended design would have performed.

184. The subject drugs failed to perform as safely as their intended design because, among other potential defects, they contained unsafe levels of NDMA and NDEA.

185. Plaintiff and the Class members used the products as intended and in a manner reasonably foreseeable to Defendants.

186. As a direct and proximate result of the manufacturing defect in the subject drugs, Plaintiff and the Class members have suffered loss and damages.

187. Specifically, the defective nature of the subject drugs proximately caused Plaintiff and the Class members experience significantly increased risk for suffering several types of cancer as alleged above, thus requiring future monitoring and the costs associated with such.

188. Wherefore, Plaintiff, individually and on behalf of the Class, prays for relief as set forth below against all Defendants.

COUNT IV: MEDICAL MONITORING
On Behalf of Plaintiff and the Class

189. Plaintiff hereby incorporates by reference all previous allegations as if alleged herein.

190. NDMA and NDEA have been proven to be hazardous substances.

191. The latency period may be many years for NDMA- and NDEA-related cancers.

192. As a direct and proximate result of ingesting the subject drugs, Plaintiff and each Class Member was exposed to levels of NDMA and NDEA that exceed background levels of those compounds.

193. Plaintiff's and the Class members' exposure to NDMA and NDEA was a direct and proximate result of Defendants' negligence.

194. Plaintiff's and the Class members' exposure to NDMA and NDEA was a direct and proximate result of the design defect in the subject drugs.

195. Plaintiff's and the Class members' exposure to NDMA and NDEA was a direct and proximate result of the manufacturing defect in the subject drugs.

196. As a direct and proximate result their exposure to NDMA and NDEA through ingestion of the subject drugs, Plaintiff and each Class Member has a significantly increased risk of contracting a latent disease or diseases including (a) liver cancer; (b) intestinal cancers (including colorectal cancer); (c) stomach cancer; (d) kidney cancer; (e) pancreatic cancer; and esophageal cancer.

197. Monitoring procedures exist that make the early detection of these diseases possible.

198. Such monitoring procedures are different from those normally recommended in the absence of exposure to NDMA and NDEA.

199. Such monitoring procedures are reasonably necessary for Plaintiff and all members of the proposed Class based on contemporary scientific principles.

200. Advances in science and medicine may reveal during the pendency of this action and/or during the monitoring period additional latent diseases for which Plaintiff and each Class

Member has a significantly increased risk due proximately to their exposure to NDMA and NDEA as a result of the Defendants' negligence and the product defects identified above.

201. As a direct and proximate result of the Defendants' negligence and other wrongful conduct and due to the defective nature of the subject drugs as alleged above, Plaintiff and each Class member will suffer and will continue to suffer the costs of periodic medical examinations necessary to detect the onset of physical harm caused by NDMA and/or NDEA.

202. Wherefore, Plaintiff individually and on behalf of the class, prays for relief as set forth below against all Defendants.

DEMAND FOR JURY TRIAL

203. Plaintiff, individually and on behalf of the Class, demands trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of the Class, respectfully demands judgment against Defendants, and each of them, individually, jointly and severally and requests all relief available at law or in equity, including, but not limited to the following:

A. an order that certifies the proposed Class, designates Plaintiff as class representative, and appoints the undersigned as Class counsel;

B. an order and judgment for the quantifiable costs of periodic medical examinations of Plaintiff and the Class necessary to detect the onset of all diseases and physical harms for which Plaintiff and the Class are at significantly increased risk of contracting, including but not limited to the cancers identified in this Complaint;

C. an order awarding Plaintiff and the Class any other damages to which they may be entitled at law or in equity, including reasonable attorneys' fees and costs of this action;

D. an award of pre-judgment and/or post-judgment interest to the extent permitted by law or in equity;

E. such other relief as the Court may deem appropriate.

Dated: 5/24/2019

Respectfully Submitted,

/s/*Daniel A Nigh*
Daniel A. Nigh (Fla. Bar No. 30905)
Levin, Papantonio, Thomas, Mitchell, Rafferty & Proctor, P.A.
316 S. Baylen Street, Suite 600
Pensacola, FL 32502
Phone: (850) 435-7013
Fax: (850) 436-6013
Email: dnigh@levinlaw.com

Matthew D. Schultz (Fla. Bar No. 640328)
Levin, Papantonio, Thomas, Mitchell, Rafferty & Proctor, P.A.
316 S. Baylen Street, Suite 600
Pensacola, FL 32502
Phone: (850) 435-7140
Fax: (850) 436-6140
Email: mschultz@levinlaw.com

Brenton J. Goodman (Fla. Bar No. 126153)
Levin, Papantonio, Thomas, Mitchell, Rafferty & Proctor, P.A.
316 S. Baylen Street, Suite 600
Pensacola, FL 32502
Phone: (850) 435-7171
Fax: (850) 436-6140
Email: bgoodman@levinlaw.com

JS 44 (Rev. 08/16)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Sarah Zehr

(b) County of Residence of First Listed Plaintiff Santa Rosa County, FL
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Daniel A. Nigh; Levin Papantonio Law Firm; 316 South Baylen Street, Suite 600; (850) 435-7000

DEFENDANTS

ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., PRINSTON PHARMACEUTICAL, INC., dba SOLCO HEALTHCARE U.S., LLC, SOLCO HEALTHCARE US, LLC, and HUAHAI U.S., INC.,

County of Residence of First Listed Defendant Middlesex County, NJ
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☒ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

- ☐ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District *(specify)*
- ☐ 6 Multidistrict Litigation - Transfer
- ☒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. 1332

Brief description of cause:
Products Liability

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ 9,000,000,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Robert B. Kugler DOCKET NUMBER 19-2875

DATE 05/24/2019

SIGNATURE OF ATTORNEY OF RECORD /s/Daniel A. Nigh

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

Print Save As... Reset